NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC., KING PHARMACEUTICALS, RESEARCH AND DEVELOPMENT, INC., and WYETH	:	
Plaintiffs,	:	Civil Action No. 05-3855 (JAP)
v.	:	**OPINION**
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	

APPEARANCES:

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PISANO, District Judge.

Plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (together, "King") and involuntary Plaintiff Wyeth[1] brought this action for patent infringement against Defendant Teva Pharmaceuticals USA, Inc. ("Teva"). King alleges that Teva has infringed one or more claims of United States Patent No. 4,626,538 ("the 538 Patent"). This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Teva now moves for summary judgment on Plaintiffs' claims, arguing that the 538 Patent expired on June 12, 2003, and thus no valid and enforceable patent is being asserted. For the reasons expressed below, the Court denies Teva's motion for summary judgment.

I. BACKGROUND

This is an action for patent infringement of the 538 Patent,[2] under which King has the right, *inter alia*, to sell prescription zaleplon drug products in the United States. King sells Sonata®, a prescription zaleplon drug that is used to treat insomnia. The 538 Patent issued in

[1] King named Wyeth as an involuntary plaintiff to this action pursuant to Federal Rule of Civil Procedure 19.

[2] The 538 Patent is entitled "[7-(3-Distributed Amino)PhenylPyrazolo[1,5-a]Pyrimidines." (Compl. ¶ 9; Compl. Ex. A).

1986 subject to a terminal disclaimer[3] that originally set the expiration date of the 538 Patent to coincide with the expiration date of United States Patent Nos. 4,654,347 ("the 347 Patent") and 4,521,422 ("the 422 Patent"). The 347 and 422 Patents expired on June 23, 2003. On June 4, 2003, however, pursuant to 35 U.S.C. § 156, the United States Patent and Trademark Office ("PTO") extended the term of the 538 Patent for a period of 1810 days. By operation of the § 156 Patent Term Extension, the 538 Patent will expire on June 6, 2008. The Patent Term Extension did not apply to the 347 and 422 Patents, which do not cover Sonata®.

The terminal disclaimer included a provision requiring common ownership of the 538, 347, and 422 Patents. In the event that common ownership of the patents ceased to exist, the terminal disclaimer would be unenforceable:

> Your petitioner . . . hereby disclaims the terminal part of any patent granted on the above-identified application . . . and hereby agrees that any patent so granted on the above-identified application *shall be enforceable only for and during such period that the legal title to said patent shall be the same as [the 347 and 422 Patents]* . . . .

(Wamsley Decl., Ex. A (Terminal Disclaimer dated Apr. 21, 1986)) (emphasis added). On June 12, 2003, eleven days prior to the expiration of the 347 and 422 Patents but after the 538 Patent Term Extension, Wyeth transferred some of its rights in the 538 Patent to King via two related agreements: the Patent Assignment and the Asset Transfer Agreement. In relevant part, the Patent Assignment states:

> [Wyeth] assigns and transfers to [King], . . . subject to the conditions of the [Asset] Transfer Agreement and other Related Agreements, such assignment and

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[3] The purpose of a terminal disclaimer is to overcome a patent rejection for obviousness-type double patenting, *i.e.*, where the same inventor or joint inventors file two patent applications for substantially the same invention. The filing of a terminal disclaimer permits the issuance of the second patent, but with the same expiration date as the first patent.

> transfer, an undivided right, title and interest in and to the [538] Patent Rights . . . to be held and enjoyed by [King], for [King]'s own use and benefit . . . to the full end of the term or terms for which said patent(s) may be granted, subject only to the conditions of the Transfer Agreement and the Related Agreements.

(Wamsley Decl., Ex. B (Patent Assignment dated June 12, 2003)). The Asset Transfer Agreement, which the Patent Assignment expressly incorporates, provides that King received the right to sell prescription zaleplon products, while Wyeth retained all rights related to over-the-counter zaleplon products ("OTC Products") and zaleplon animal health products ("Animal Health Products"): "Wyeth has not conferred upon [King] any right, to make, have made, use, sell, offer for sale, import, develop, distribute, market or otherwise commercialize Zaleplon . . . as Animal Health Products or OTC . . . ." (Wamsley Decl., Ex. C (Asset Transfer Agreement at § 3.08; *see also* § 1.02)). Additionally, Wyeth retained all rights related to the international manufacture and sale of zaleplon products. (*See id.* at § 3.08.)

This action arose after Teva filed Abbreviated New Drug Application No. 77-239 ("ANDA No. 77-239") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of King's Sonata® drug products. In a June 20, 2005 notification letter, Teva informed King and Wyeth that it had submitted ANDA No. 77-239 to the FDA seeking approval to engage in the commercial manufacture, use, and sale of zaleplon capsules. (Compl. ¶¶ 15, 16). King filed a Complaint on August 2, 2005 alleging that Teva's ANDA filing constitutes patent infringement and that, if the FDA approves Teva's ANDA, Teva will infringe the 538 Patent by, *inter alia*, manufacturing and selling zaleplon capsules in the United States. King seeks declaratory and injunctive relief, damages, counsel fees, and costs and expenses.

On September 22, 2005, Teva moved to dismiss the Complaint for failure to state a claim upon which relief can be granted, arguing that the 538 Patent expired on June 23, 2003 because, in Teva's view, the term of a terminally disclaimed patent may not be extended under 35 U.S.C. § 156. In a published opinion dated January 20, 2006, this Court denied Teva's motion, finding that neither § 156 nor any other provision of law renders "terminally disclaimed patents ineligible for a § 156 extension." *King Pharma, Inc. v. Teva Pharma, Inc.*, 409 F. Supp. 2d 609, 614, 615-18 (D.N.J. 2006). On September 25, 2006, Teva conceded via a Stipulation of Infringement that if the Court finds the 538 Patent to be valid and enforceable, Teva's proposed manufacture and sale of zaleplon capsules would infringe the patent. (*See* Dkt. #52 (Stipulation of Infringement dated Sept. 25, 2006)). Teva now moves for summary judgment on King's claims for patent infringement on the grounds that the 538 Patent expired on June 12, 2003, when, in Teva's view, common ownership of the 347, 422, and 538 patents dissolved.

II. DISCUSSION

A. Standard of Review under Federal Rule of Civil Procedure 56(c)

Summary judgment is appropriate under Federal Rule of Civil Procedure 56(c) "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact, and that the moving party is entitled to judgment as a matter of law." The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The burden then shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at

324. In so presenting, the non-moving party must offer specific facts that establish a genuine issue of material fact, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

B. Analysis

In Teva's view, the June 12, 2003 Asset Transfer Agreement was an assignment of legal title and all substantial rights in the 538 Patent from Wyeth to King. This assignment, according to Teva, violated the terminal disclaimer because the assignment resulted in a division of ownership of the three relevant patents: King became the owner of the 538 Patent while Wyeth retained ownership of the 347 and 422 Patents. Teva further argues that the subsequent expiration of the 347 and 422 Patents, on June 23, 2003, does not cure King's violation of the terminal disclaimer or render the terminal disclaimer enforceable in any period after June 23, 2003.

King responds that, regardless of the titles that the parties used, the Asset Transfer Agreement was not an assignment. Instead, King acquired from Wyeth an exclusive rights license to sell prescription zaleplon drug products in the United States under the 538 Patent.

King further contends that, even if the Asset Transfer Agreement resulted in an assignment of the 538 Patent, the terminal disclaimer's common ownership requirement is irrelevant because the June 4, 2003 Patent Term Extension does not require common ownership of the 347, 422, and 538 Patents. Alternatively, King argues that there could not be common ownership of the three patents during the period in which King claims that Teva infringed the 538 Patent (from June 23, 2003 to the present) because the 347 and 422 Patents expired on June 23, 2003. In other words, King argues that one cannot own that which does not exist.

As explained below, having analyzed the substance of the agreement between Wyeth and King, the Court finds that King was a mere licensee of the 538 Patent. Thus, Wyeth continued to own the 347, 422, and 538 Patents after the execution of the Patent Assignment and Asset Transfer Agreement. Because the Patent Assignment and Asset Transfer Agreement did not sever common ownership of the patents, there was no violation of the terminal disclaimer. Therefore, the 538 Patent is valid and enforceable. Having reached this conclusion, it is unnecessary for the Court to decide whether (1) the expiration of the 347 and 422 Patents would have cured a violation of the terminal disclaimer or (2) whether a § 156 Patent Term Extension nullifies the requirements of a terminal disclaimer.

It is well settled that "[w]hether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions." *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891); *see also Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 874 (Fed Cir. 1991) ("To determine whether a provision in an agreement constitutes an assignment or license, one must ascertain the intention of the parties and examine the substance of what was granted."). A

patent assignment occurs where there is a transfer of all substantial rights to the patent; anything less than a transfer of all substantial rights is a license. *See Vaupel*, 944 F.2d at 874; *see also Intellectual Prop. Dev. Inc. v. TCI Cablevision*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) ("A grant of all substantial rights in a patent amounts to an assignment."); *E.I. du Pont de Nemours & Co. v. United States*, 432 F.2d 1052, 1055 (3d Cir. 1970) ("[A] transfer of all the substantial rights in a patent is deemed an assignment . . . anything less is called a license . . . ."). Substantial rights in a patent include "(1) the exclusive right to make, use, and sell under the patent; (2) the right to transfer; and (3) the right to sue infringers." *McNeilab, Inc. v. Scandipharm, Inc.*, 862 F. Supp. 1351, 1356 (E.D. Pa. 1994); *see also Raber v. Pittway Corp.*, No. 91-2399, 1992 WL 219016 (N.D. Cal. May 4, 1992), *aff'd* 996 F.2d 318 (Fed. Cir. 1993).[4] "[I]n determining whether a grant of all substantial rights was intended, it is helpful to look at what rights have been retained by the grantor, not only what was granted." *Vaupel*, 944 F.2d at 875.

The documents that embody the agreement between King and Wyeth—the Patent Assignment and the Asset Transfer Agreement—demonstrate that Wyeth did not transfer to King all substantial rights in the 538 Patent. The Patent Assignment states:

> [Wyeth] assigns and transfers to [King], . . . subject to the conditions of the [Asset] Transfer Agreement and other Related Agreements, such assignment and transfer, an undivided right, title and interest in and to the [538] Patent Rights . . . to be held and enjoyed by [King], for [King]'s own use and benefit . . . to the full end of the term or terms for which said patent(s) may be granted, subject only to the conditions of the Transfer Agreement and the Related Agreements.

(Wamsley Decl., Ex. B (Patent Assignment)). Although, as Teva points out, the Patent Assignment grants King "an undivided right, title and interest in and to the [538] Patent Rights,"

[4] *Raber* can also be found at 23 U.S.P.Q.2d 1313.

that language alone does not resolve the matter because the transfer is "subject to the conditions of the [Asset] Transfer Agreement and other Related Agreements." (*Id.*) Thus, in order to determine the substance of the transfer, the Court must analyze the relevant provisions of the Asset Transfer Agreement.

Pursuant to Section 1.01 of the Asset Transfer Agreement, Wyeth transferred to King the "Acquired Assets," as defined in the agreement. The "Acquired Assets," as defined, specifically exclude OTC Products and Animal Health Products:

> The term "Acquired Assets" means all of Wyeth's and its Affiliates' rights, title and interest in, to and under those certain assets (in each case only to the extent necessary to (a) conduct the Business, (b) in the Territory, have exclusive rights with respect to zaleplon (*other than OTC Products or Animal Health Products*), Products and/or Line Extensions; and/or (c) enjoy rights with respect to New Formulations (*other than OTC Products or Animal Health Products*) . . .

(Wamsley Decl., Ex. C (Asset Transfer Agreement at § 1.01)) (emphasis added). Section 3.08 of the Asset Transfer Agreement reiterates this point and provides that Wyeth retains the right, *inter alia*, to manufacture and sell zaleplon products outside of the United States, its territories and possessions (referred to as the "Territory"):

> [P]ursuant to this Agreement, Wyeth has not conferred upon [King] any right, to make, have made, use, sell, offer for sale, import, develop, distribute, market and otherwise commercialize Zaleplon . . . outside the Territory, and, within the Territory . . . to make, have made, use, sell, offer for sale, import, develop, distribute, market and otherwise commercialize Zaleplon . . . as Animal Health Products or OTC Products . . . .

(*Id.* at § 3.08). By express provision of the Asset Transfer Agreement, Wyeth retained all rights to manufacture and sell over-the-counter zaleplon products and zaleplon products designed to treat animals, and to manufacture and sell zaleplon products outside of the United States, its territories and possessions. It is thus indisputable that King does not enjoy a right of exclusivity

under the 538 Patent. Further, King does not have the right to transfer any interest in the 538 Patent pertaining to OTC Products, Animal Health Products, and the international manufacture and sale of zaleplon. Nor may King sue for infringement of those rights. Indeed, the only rights that King received, and currently enjoys, are those related to the manufacture and sale of *prescription* zaleplon products within the United States, its territories and possessions.

Moreover, pursuant to Section 5.08 of the Asset Transfer Agreement, King may not even assign the rights it does hold under the 538 Patent without Wyeth's written consent. *See Raber*, 1992 WL 219016, at *3 (finding that restriction on alienation demonstrates reservation of substantial rights). Thus, it cannot be said that Wyeth transferred all substantial rights in the 538 Patent to King. *See McNeilab, Inc.*, 862 F. Supp. at 1356 (stating the substantial rights under patent include exclusivity, right to transfer, and right to sue for infringement); *Raber*, 1992 WL 219016, at *2 (same). The Court therefore concludes that the Patent Assignment and Asset Transfer Agreement constitute a license of the 538 Patent from Wyeth to King granting King rights related only to prescription zaleplon products.

Teva nevertheless argues that, as a matter of logic, King must have received legal title of the 538 Patent because King granted Wyeth an exclusive license related to OTC Products, Animal Health Products, and the international manufacture and sale of zaleplon. (*See* Wamsley Decl., Ex. C (Asset Transfer Agreement at § 3.08)). In Teva's view, it would be impossible for King to grant Wyeth such a license unless it held legal title to the 538 Patent. Teva fails to note, however, that Section 3.08 of the Asset Transfer Agreement also includes a license from Wyeth to King "to make or have made Zaleplon . . . within and without the [United States], but only for sale to and use by end users who are within the [United States]." (*Id.*) That the Asset Transfer

Agreement purports to carve out these licenses is proof only that the document contains some superfluous provisions and tortured language, not that Wyeth assigned the 538 Patent to King.

Further, the Court is not persuaded by Teva's argument that the transfer is an assignment because the parties memorialized their agreement in a document entitled "Patent Assignment" and recorded the Patent Assignment in the PTO. First, as *Waterman* and its progeny make clear, the determination of whether a transfer of rights constitutes an assignment depends upon the substance of that transfer, not the title that the parties use to describe it. *Waterman*, 138 U.S. at 256; *Vaupel*, 944 F.2d at 874. As explained above, the express provisions of the Patent Assignment and Asset Transfer Agreement establish that King did not receive all substantial rights in the 538 Patent. Thus, although the agreement documents contain some misleading language, the substance of the transfer demonstrates conclusively that King merely has a license under the 538 Patent to manufacture and sell prescription zaleplon products in the United States, it territories and possessions.

Secondly, "the mere fact that an assignment was recorded in the [PTO] does not, without more, prove that a valid assignment actually took place." *COR Marketing & Sales, Inc. v. Greyhawk Corp.*, 994 F. Supp. 437, 444 (W.D.N.Y. 1998); 37 C.F.R. § 3.54 (1995) ("The recording of a document . . . is not a determination by the [PTO] of the validity of the document of the effect the document has on the title to an application, a patent, or a registration."). In finding that the transfer at issue in *Greyhawk* was an assignment, the court noted that the patent assignment recorded in the PTO was not subject to or conditioned upon any other related agreements. *See Greyhawk*, 994 F. Supp. at 444. Here, unlike *Greyhawk*, the Patent Assignment expressly provides that it is subject to and conditioned upon the Asset Transfer Agreement,

which makes clear that Wyeth retained substantial rights in the 538 Patent.

Finally, the Court finds support for its conclusion in *Raber v. Pittway Corp.* In that case, the plaintiff (Raber) asserted that he obtained "the entire right, title and interest in" the patent-in-suit based upon an assignment document recorded with the PTO. *Raber*, 1992 WL 219016, at *1. The transfer set forth in the recorded document appeared to be an assignment of all rights in the patent-in-suit from Cerberus to Raber. *Id.* Like the Patent Assignment in this case, however, the recorded document in *Raber* was subject to an unrecorded side agreement, in which Cerberus retained some substantial rights in the patent-in-suit. *Id.* at *3. In the *Raber* court's view, the fact that the side agreement contained language purporting to grant a license from Raber to Cerberus did not establish proof that Raber held legal title and all substantial rights in the 538 Patent. To the contrary, the license, along with a provision in the side agreement that Raber could not assign his interest in the patent-in-suit without permission from Cerberus, formed the basis for the court's conclusion that Raber was a "mere licensee, not an assignee." *Id.*

Having concluded that King, as a licensee, does not hold legal title to the 538 Patent, and that Wyeth maintained common ownership of the 347, 422, and 538 Patents until the 347 and 422 Patents expired on June 23, 2003, the Court finds that Wyeth's transfer of rights in the 538 Patent to King did not render the terminal disclaimer unenforceable. Thus, the 538 Patent is valid and enforceable. Consequently, the Court need not resolve the question of whether the expiration of the 347 and 422 Patents is an event that cures a violation of the terminal disclaimer or whether a Patent Term Extension nullifies the requirements of a terminal disclaimer.

III. CONCLUSION

For the reasons expressed above, the Court denies Teva's motion for summary judgment. An appropriate order accompanies this opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: January 22, 2007